



ROPES & GRAY LLP
PRUDENTIAL TOWER
800 BOYLSTON STREET
BOSTON, MA 02199-3600
WWW.ROPESGRAY.COM

July 6, 2011

Brien T. O'Connor
T +1 617 951 7385
F +1 617 235 0084
brien.o'connor@ropesgray.com

Hon. George A. O'Toole
United States District Court
John Joseph Moakley United States Courthouse
1 Courthouse Way
Boston, MA 02210

Re: *United States v. Stryker Biotech, LLC et al.*, Case No. 09-CR-10330-GAO

Dear Judge O'Toole:

I write on behalf of the five Defendants in the above-captioned case, who submit this brief reply to the government's July 1, 2011 letter to the Court regarding the import of *Sorrell v. IMS Health, Inc.*, 564 U.S. ___, 2011 WL 2472796 (June 23, 2011), to the pending motions to dismiss.

Arguing that *Sorrell* is "irrelevant" to this case, the government asserts that defendants "provided mixing recipes for OP-1 and Calstrux despite the facts that the mixture was never clinically tested and the FDA had not approved the safety or efficacy of the mixture," as if such conduct is inherently nefarious. Perhaps the Vermont legislators who enacted the provisions of the Prescription Confidentiality Law prohibiting the sale to manufacturers of pharmacy records containing physician prescribing information believed such sales—and conspiring to make them—also to be inherently nefarious acts. *See* Vt. Stat. Ann., Tit. 18, § 4631 (Supp. 2010). The Supreme Court nonetheless has now clearly held that the First Amendment prohibits this type of restriction on speech.

In light of *Sorrell*, it is cavalier for the government to assert that the First Amendment simply has no bearing on whether salespersons can give surgeons unadorned directions on mixing two products, regardless of whether the directions have been clinically tested or approved by the FDA. These directions were speech that anyone other than Stryker Biotech and its representatives could have distributed with complete impunity. The misbranding regulations prohibiting Stryker Biotech from engaging in such speech are just as content-based and viewpoint-discriminatory as the Vermont law struck down by *Sorrell*, and similarly should be considered every bit as constitutionally suspect.

For the above reasons and those in our prior submissions, Defendants respectfully request that the Court dismiss Counts 7-14 and the offense prong of Count 6. To convict the Defendants of

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fraud, the government should be required to prove actual fraud, not the commission of constitutionally protected conduct.

Respectfully submitted,

A handwritten signature in cursive script that reads "Brien T. O'Connor". The signature is written in dark ink and is positioned above the printed name.

Brien T. O'Connor

BTO:cal